



Office of the Chief Counsel Food and Drug Administration 5600 Fishers Lane, GCF-1 Rockville, MD 20857

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February 7, 2005

Departmental Appeals Board Room 637-D Hubert H. Humphrey Bldg. 200 Independence Avenue, S.W. Washington, D.C. 20201

Dockets Management Branch (HFA-305) Food and Drug Administration, Room 1061 5630 Fishers Lane Rockville, MD 20857

Re: In re Korangy Radiology Associates, P.A., et al. FDA Docket No. 2003H-0432

Dear Sir or Madam:

Enclosed for filing in the above-captioned matter is the original and one copy of Complainant's Motion for Extension of Time for Complainant to File its Response to Respondents' Appeal and a Proposed Order. If you have any questions, please call me at (301) 827-1189. Thank you.

Sincerely,

Marci B. Norton

Associate Chief Counsel

Marci B. Norton

for Enforcement

Enclosure

cc w/encl.:

Henry E. Schwartz, Esq.

BEFORE THE DEPARTMENTAL APPEALS BOARD DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of) FOOD AND DRUG ADMINISTRATION

KORANGY RADIOLOGY ASSOCIATES, P.A.,) ADMINISTRATIVE COMPLAINT a corporation,) FOR CIVIL MONEY PENALTY and) FDA Docket: 2003H-0432

AMILE A. KORANGY, M.D., an individual.)

MOTION FOR EXTENSION OF TIME FOR COMPLAINANT TO FILE ITS RESPONSE TO RESPONDENTS' APPEAL

Counsel for the Center for Devices and Radiological Health (CDRH) hereby respectfully requests, pursuant to 21 C.F.R. § 17.47(b)(2), that the Departmental Appeals Board (DAB) grant a ten-day extension of time for Complainant to file its response to Respondents' appeal. CDRH's counsel has conferred with defendants' counsel, Henry Schwartz, and Mr. Schwartz does not oppose a ten-day extension for CDRH to file its response.

Respondents filed their appeal on January 13, 2005. Under 21 C.F.R. § 17.47(d), Complainant's response is due within thirty of receiving the notice of appeal and accompanying brief, which is February 14, 2005. Respondents raise numerous issues in their appeal that Complainant intends to address thoroughly in its response, however, Complainant's counsel have additional court deadlines within the time remaining for it to file its response

to Respondents' appeal. Additionally, one of Complainant's attorneys will be on travel for work the entire week of February 7, 2005. Accordingly, Complainant respectfully requests a ten day extension of time for responding to the appeal, making its response due on February 24, 2005. Complainant makes this request for extension of time within the initial 30-day period for responding, as required under 21 C.F.R. § 17.47(b)(2). DATED: February 7, 2005.

Respectfully submitted,

Marci B. Norton

Attorney for Complainant

Center for Devices and Radiological Health

5600 Fishers Lane (GCF-1)

Rockville, MD 20857

Telephone: (301) 827-1189

BEFORE THE DEPARTMENTAL APPEALS BOARD DEPARTMENT OF HEALTH AND HUMAN SERVICES

PROPOSED ORDER

On February 7, 2005, Complainant, Center for Devices and Radiological Health, filed a Motion for Extension of Time for Complainant to File its Response to Respondents' Appeal, requesting an additional ten days to file its response. Counsel for defendants does not oppose Complainant's request. The Departmental Appeals Board has determined that good cause exists for an extension of time.

Accordingly, it is ORDERED, ADJUDGED, AND DECREED that:

Complainant's request for an additional ten days to file its response to Respondent's appeal is GRANTED, and Complainant's response is now due on February 24, 2005.

Departmental Appeals Board Room 637-D Hubert H. Humphrey Bldg. 200 Independence Avenue, S.W. Washington, D.C. 20201

Proposed by:

Marci B. Norton

Attorney for Complainant

CERTIFICATE OF SERVICE

I hereby certify that, on this 7th day of February, 2005, I have caused a copy of the foregoing Motion for Extension of Time for Complainant to File its Response to Respondents' Appeal and Proposed Order to be served by Federal Express overnight delivery, on:

Henry E. Schwartz Henry E. Schwartz LLC Attorney for Respondents 901 Dulaney Valley Road, Suite 400 Towson, MD 21204

Marci B. Norton

Attorney for Complainant 5600 Fishers Lane (GCF-1)

Rockville, MD 20857